

1. An assembly for anchoring soft tissue or artificial grafts in bone, comprising:
  - an insertion element comprising a stem and an aperture-containing stem head proximal to said stem, said aperture being of a size sufficiently large to receive a soft tissue graft; and
  - 5 a stabilizing element adapted to be embedded in bone comprising a sleeve having a cavity, said cavity being arranged and constructed so as to receive and hold said stem.
2. An assembly for anchoring soft tissue grafts in bone, comprising:
  - 10 an insertion element comprising a stem and an aperture-containing stem head proximal to said stem, said aperture being of a size sufficiently large to receive a soft tissue graft; and
  - a stabilizing element adapted to be embedded in bone comprising a sleeve having a cavity, said cavity being elongated and having an inner
  - 15 diameter slightly smaller than an outer diameter of said stem, such that said sleeve is capable of holding said stem by compression fit.
3. An assembly according to claims 1 or 2, wherein the insertion element further comprises any of an aperture, slot, and barb by which said insertion element
- 20 can be pulled into said bone hole.
4. An assembly according to claim 3, wherein said any of an aperture, slot and barb is disposed at the distal end of the insertion element.
- 25 5. An assembly according to claims 1 or 2, wherein at least one of said stem of said insertion element and said sleeve of said stabilizing element are elongate and have protrusions on their outer surfaces.
6. An assembly according to claim 5, wherein said protrusions on said stabilizing
- 30 element comprise threading amenable to being screwed into an opening drilled into bone.

7. An assembly according to claims 1 or 2, wherein said stabilizing element comprises a flange at its distal end, whereby upon embedding of the stabilizing element in the bone hole, the flange is disposed at least partially outside the bone hole in a configuration whereby it will oppose any further movement of the stabilizing element into the bone hole.
8. An assembly according to claims 1 or 2, wherein said cavity comprises an axial channel, the cross-section of said channel being non-cylindrical, said axial channel extending between proximal and distal ends of said elongated sleeve.
9. An assembly for anchoring soft tissue grafts in bone, comprising:  
an insertion element comprising an elongated stem and an aperture-containing stem head proximal to said stem, said aperture suitably sized for passage of a soft tissue graft therethrough; and  
a stabilizing element capable of insertion into an opening drilled into bone and comprising an elongated sleeve having an axial channel, said channel having a diameter slightly smaller than that of said elongated stem of said insertion element such that said stabilizing element will expand upon insertion of said insertion element into said channel.
10. The assembly according to claim 9, wherein the insertion element further comprises any of an aperture, slot, or barb by which said insertion element can be pulled into said bone hole.
11. An assembly according to claim 9 or 10, wherein a cross-section of said axial channel is non-cylindrical.
12. The assembly according to claim 11, wherein said stabilizing element can be deformably expanded to obtain a pressure fit within a bone opening upon insertion of said insertion element into said non-cylindrical aperture of said stabilizing element.

13. The assembly according to claims 1, 2, 9 or 10, wherein said insertion and stabilizing elements comprise bio-compatible material.
14. The assembly according to claims 1, 2, 9 or 10, wherein said stabilizing element has a fanged proximal end.
15. An assembly for anchoring soft tissue grafts into bone, comprising:  
an insertion element comprising an elongated stem and aperture-containing stem head proximal to said stem, said aperture being of a size sufficiently large to receive a soft tissue graft; and  
a stabilizing element adapted to be embedded in bone comprising a elongated sleeve with external threads and an axial channel passing therethrough, said axial channel having a non-cylindrical cross-section such that an emplacement device can be inserted therein for screwing said threads of said stabilizing element into said bone.
16. The assembly according to claim 15, wherein the insertion element further comprises any of an aperture, slot, and barb by which said insertion element can be pulled into said bone hole.
17. An assembly according to claim 10 or 16, wherein said any of an aperture, slot and barb is disposed at the distal end of the insertion element.
18. The assembly of claim 1, 2, 9, or 15, further comprising:  
a second insertion element comprising a stem and an aperture-containing stem head proximal to said stem, said aperture being of a size sufficiently large to receive a soft tissue graft; and  
a second stabilizing element adapted to be embedded in bone comprising a sleeve having a cavity, said cavity being arranged and constructed so as to receive and hold the stem of the second insertion element.

19. The assembly of claim 18, wherein at least one of the insertion element and the second insertion element further comprises any of an aperture, slot, or barb by which said insertion element can be pulled into said bone hole.

5 20. The assembly of claim 18, wherein at least one of the stabilizing element and the second stabilizing element comprises a flange at its distal end, whereby upon embedding of the stabilizing element in the bone hole, the flange is disposed at least partially outside the bone hole in a configuration whereby it will oppose further movement of the stabilizing element into the bone hole

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21. A method for anchoring soft tissue within bone comprising: drilling an opening into bone;  
inserting into said bone opening a stabilizing element comprising an elongated sleeve with an axial channel extending therethrough;  
15 threading soft tissue through an aperture in an insertion element comprising an aperture-containing stem head proximally located to an elongated stem, said stem having a diameter slightly larger than that of said axial channel of said elongated sleeve; and  
inserting the distal end of said insertion element into proximal end of said  
20 stabilizing element.

22. A method according to claim 21, wherein said soft tissue is a tendon.

23. A method according to claim 21, wherein the method of drilling said opening  
25 comprises creating a stepped opening.

24. A method according to claim 23, wherein the stepped opening has at least two different diameters, one less than the diameter of the stabilizing element, and one greater than the diameter of the stem head.

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25. A method according to claim 24, wherein said elongated sleeve of said stabilizing element is screwed into said bone opening at the diameter where said stepped bone opening is slightly smaller than that of said elongated sleeve.
- 5 26. A method according to claim 25, wherein said axial channel in the stabilizing device is non-cylindrical, and wherein said stabilizing element is screwed into said stepped bone opening by use of an emplacement device fitted into said non-cylindrical axial channel.
- 10 27. A method according to claim 21, wherein said insertion element retaining said soft tissue is inserted forcibly into said stabilizing element screwed into said stepped bone hole.
- 15 28. A method according to claim 21, wherein said stabilizing element comprises a flange at its distal end, whereby upon insertion of the stabilizing element in the bone opening, the flange is disposed at least partially outside the bone opening in a configuration whereby it will oppose further movement of the stabilizing element into the bone opening.
- 20 29. A method for anchoring soft tissue within bone comprising:  
drilling an opening into bone;  
inserting into said bone a stabilizing element comprising an elongated sleeve  
with an axial channel extending therethrough;  
threading soft tissue through an aperture in an insertion element comprising an  
25 aperture containing stem head proximally located to an elongated  
stem, said stem having a diameter slightly larger than that of said  
axial channel of said elongated sleeve; and  
pulling the distal end of said insertion element into proximal end of said  
stabilizing element.
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30. The method of claim 21 or 29, further comprising:

drilling a second opening into bone;

inserting into said second bone opening a second stabilizing element

comprising an elongated sleeve with an axial channel extending  
therethrough;

threading the soft tissue through an aperture in a second insertion element  
comprising an aperture-containing stem head proximally located to an  
elongated stem, said stem having a diameter slightly larger than that  
of said axial channel of said elongated sleeve; and

inserting the distal end of said second insertion element into proximal end of  
said second stabilizing element.

31. The method of claim 30 wherein at least one of the stabilizing element and the

second stabilizing element comprises a flange at its distal end, whereby upon  
insertion of the stabilizing element into a bone opening, the flange is disposed  
at least partially outside the bone opening in a configuration whereby it will  
oppose further movement of the stabilizing element into the bone opening.

32. A method for replacing a torn ligament comprising:

obtaining a tendon graft;

drilling a hole into bone;

looping said tendon graft through an aperture in an insertion element;

inserting a stabilizing element comprising a sleeve with a cavity therein into  
said hole; and

inserting an insertion element comprising a stem with an aperture-containing  
stem head at the proximal end of said stem into said stabilizing  
element.

33. The method of claim 32 wherein said ligament is an anterior cruciate ligament and

said bone aperture is in either a femur or tibia.

34. The method of claim 32, further comprising:

drilling a second opening into bone;

inserting into said second bone opening a second stabilizing element

comprising an elongated sleeve with an axial channel extending  
therethrough;

looping the tendon graft through an aperture in a second insertion element  
comprising an aperture-containing stem head proximally located to an  
elongated stem, said stem having a diameter slightly larger than that  
of said axial channel of said elongated sleeve; and

inserting the distal end of said second insertion element into proximal end of  
said second stabilizing element.

35. The method of claims 21 or 32 wherein said stabilizing element is affixed into  
bone by interference fit.

36. The method of claims 21 or 32 wherein said stabilizing element comprises a  
flange at its distal end, whereby upon insertion of the stabilizing element into a  
bone opening, the flange is disposed at least partially outside the bone opening  
in a configuration whereby it will oppose further movement of the stabilizing  
element into the bone opening.

37. A method for replacing a torn ligament comprising:

obtaining a tendon graft;

drilling a hole into bone;

looping said tendon graft through an aperture in an insertion element;

inserting a stabilizing element comprising a sleeve with a cavity therein into  
said hole; and

pulling an insertion element comprising a stem with an aperture containing  
stem head at the proximal end of said stem and any of an aperture,  
slot and barb at the distal end of said stem.

38. The method of claim 37, further comprising:

drilling a second opening into bone;

inserting into said second bone opening a second stabilizing element

comprising an elongated sleeve with an axial channel extending  
therethrough;

looping the tendon graft through an aperture in a second insertion element

comprising an aperture-containing stem head proximally located to an  
elongated stem, said stem having a diameter slightly larger than that  
of said axial channel of said elongated sleeve, and any of an aperture,

slot, and barb at the distal end of said stem; and

pulling the second insertion element into the stabilizing element.

39. The method of claim 34 or 38, wherein said ligament is an anterior cruciate

ligament, said bone opening is in a femur, and said second bone opening is in  
a tibia.

40. The method of claim 34 or 38, wherein at least one of said stabilizing element and  
said second stabilizing element is affixed into bone by an interference fit.

41. The method of claim 34 or 38, wherein at least one of said stabilizing element and  
said second stabilizing element is affixed into bone by means of screw threads:

42. The method of claim 34 or 38, wherein at least one of said stabilizing element and  
said second stabilizing element comprises a flange at its distal end, whereby  
upon insertion of the stabilizing element into a bone opening, the flange is  
disposed at least partially outside the bone opening in a configuration whereby  
it will oppose movement of the stabilizing element into the bone opening.

43. A system for ligament reconstruction, comprising

(a) at least two bone anchors, each arranged for fixation to bone and each  
comprising an aperture,



- (b) a graft having at least two ends, at least one having a filament extending therefrom,
- (c) the graft being threaded through the aperture of one of the anchors,
- (d) the filament affixing the two ends of the graft to the aperture of the other anchor.

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44. A system for ligament reconstruction, comprising

- (a) at least two bone anchors, each arranged for fixation to bone and each comprising an aperture,
- (b) a graft having at least two ends, at least one having a filament extending therefrom,
- (c) the graft being threaded through the apertures of each of the two anchors,
- (d) the filament affixing the two ends of the graft to each other.

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45. A system for ligament reconstruction, comprising

- (a) at least a first and a second bone anchor, each arranged for fixation to bone and each comprising an aperture,
- (b) a graft having at least two ends, at least one having a filament extending therefrom,
- (c) the graft being threaded through the aperture of the first anchor,
- (d) the two ends of the graft being threaded through the aperture of the second anchor, and
- (e) the filament affixing the two ends of the graft to the aperture of the first anchor.

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46. A system for ligament reconstruction, comprising

- (a) at least a first and a second bone anchor, each arranged for fixation to bone and each comprising an aperture,
- (b) at least a first and a second graft, each having at least two ends, at least one end of each graft having a filament extending therefrom,
- (c) the first graft being threaded through the aperture of the first anchor,

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- (d) the filament of the first graft affixing the two ends of the first graft to the aperture of the second anchor,
- (e) the second graft being threaded through the aperture of the second anchor, and
- 5 (f) the filament of the second graft affixing the two ends of the second graft to the aperture of the first anchor.

47. A system for ligament reconstruction, comprising

- 10 (a) at least a first and a second bone anchor, each arranged for fixation to bone and each comprising an aperture,
- (b) at least a first and a second graft, each having at least two ends, at least one end of each graft having a filament extending therefrom,
- (c) the first graft being threaded through the aperture of the first anchor,
- (d) the filament of the first graft affixing the two ends of the first graft to the
- 15 (e) the second graft being threaded through the aperture of the first anchor, and
- (f) the filament of the second graft affixing the two ends of the second graft to the aperture of the second anchor.

20 48. The system of claim 43, 44, 45, 46, or 47, where at least one filament is a suture.

49. The system of claim 43, 44, 45, 46, or 47, where the bone anchors are embedded in bone tunnels.

25 50. The system of claim 49, where the bone tunnels are collinear.

51. The system of claim 43, 44, 45, 46, or 47, where the graft is an autologous tendon graft.

30 52. The system of claim 51, where the graft is one of a length of semitendinosus tendon and a length of gracilis tendon.

53. The system of claim 43, 44, 45, 46, or 47, where the graft is an artificial tendon graft.

54. The system of claim 43, 44, 45, 46, or 47, where the system is for repair of the anterior cruciate ligament.

55. The system of claim 43, 44, 45, 46, or 47, where at least one of the bone anchors comprises a stabilization element adapted to be affixed in bone, and an insertion element adapted to be inserted into the stabilization element.

56. A method of ligament reconstruction, comprising:

- (a) extending a filament from at least one end of a graft having at least two ends,
- (b) threading the graft through an aperture in a first bone anchor,
- (c) using the filament to affix the two ends of the graft to the aperture of the other anchor,
- (d) affixing the first anchor in bone, and
- (e) affixing the second anchor in bone.

57. A method of ligament reconstruction, comprising:

- (a) extending a filament from at least one end of a graft having at least two ends,
- (b) threading the graft through apertures in each of a first and a second bone anchor,
- (c) using the filament to affix the two ends of the graft to each other,
- (d) affixing the first anchor in bone, and
- (e) affixing the second anchor in bone.

58. A method of ligament reconstruction, comprising:

- (a) extending a filament from at least one end of a graft having at least two ends,
- (b) threading the graft through an aperture in a first bone anchor,

- (c) threading the two ends of the graft through an aperture in a second bone anchor,
- (d) using the filament to affix the two ends of the graft to the aperture of the other anchor.
- 5 (e) affixing the first anchor in bone, and
- (f) affixing the second anchor in bone.

59. A method of ligament reconstruction, comprising:

- 10 (a) extending a first filament from at least one end of a first graft having at least two ends,
- (b) extending a second filament from at least one end of a second graft having at least two ends,
- (c) threading the first graft through an aperture in a first bone anchor,
- (d) using the first filament to affix the two ends of the first graft to an aperture.
- 15 of a second bone anchor,
- (e) threading the second graft through the aperture in the second anchor,
- (f) using the second filament to affix the two ends of the second graft to the aperture in the first anchor,
- (g) affixing the first anchor in bone, and
- 20 (h) affixing the second anchor in bone.

60. A method of ligament reconstruction, comprising:

- (a) extending a first filament from at least one end of a first graft having at least two ends,
- 25 (b) extending a second filament from at least one end of a second graft having at least two ends,
- (c) threading the first graft through an aperture in a first bone anchor,
- (d) using the first filament to affix the two ends of the first graft to an aperture of a second bone anchor,
- 30 (e) threading the second graft through the aperture in the first anchor,
- (f) using the second filament to affix the two ends of the second graft to the aperture in the second anchor,

- (g) affixing the first anchor in bone, and
- (h) affixing the second anchor in bone.